

Division of Consolidated Laboratory Services (DCLS)
Virginia Environmental Laboratory Accreditation Program
(VELAP)

Technical Assistance Document
1VAC30-46

Initial Demonstration of Capability

February 25, 2020

Revised June 21, 2023

DCLS is issuing the following technical assistance concerning the initial Demonstration of Capability (DOC) determination described in the 2016 TNI Standard applicable to laboratories accredited under 1VAC30-46. Language in 2016 TNI Volume 1, Module 4 (Chemical Testing) and in Volume 1, Module 5 (Microbiological Testing) in section 1.6.2.2 of each module states, *“If the method or regulation does not specify an initial DOC, the following procedure is acceptable. It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate.”*

When a laboratory opts to document that “other approaches to initial DOC,” other than the one described in the 2016 TNI Standard, are adequate, VELAP will evaluate and make a determination on the adequacy of the laboratory’s alternate approach. This determination will be based on whether the approach is modeled after the example given in the 2016 TNI Standard in a manner which includes the following key elements for quantitative tests as laid out in the Standard’s protocol:

1. Testing in the requested quality system matrix (as defined in 1VAC30-46-40);
2. Preparation of a minimum of four (4) aliquots;
3. Testing at low-level concentration relative to the method’s testing range;
4. All analyses included in summary evaluation using mean and standard deviation or other comparable means of evaluating both accuracy and precision;
5. Evaluation of generated results against acceptance criteria for both accuracy and precision in the method (if applicable) or laboratory-generated acceptance criteria. (Note: VELAP accepts evaluation criteria specified in other approved same-technology methods if absent from the method in use); and
6. When any tested analyte fails to meet the established evaluation criteria, the source of the problem is corrected and the testing is repeated for all four replicates.

If a laboratory’s alternate approach substantially meets the key elements described above and provides justification that an equally effective substitute is in place for any key element(s) not met, VELAP may accept the alternate approach. This evaluation of the adequacy of an alternate approach by VELAP ensures that the intent of the Standard is met by all laboratories accredited under the 2016 TNI Standard.

This guidance document is also applicable to similar language in the initial DOC sections of 2016 TNI Volume 1 Module 3 (Asbestos Testing), Module 6 (Radiochemical Testing), and Module 7 (Toxicity Testing). Any questions regarding adequacy of an alternate approach for initial DOC may be submitted by e-mail to Lab_Cert@dgs.virginia.gov.